

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Walther Batsberg PEDERSEN et al.
Serial No.: New
Filing Date: December 13, 2001
For: A PROSTHETIC DEVICE

PRELIMINARY AMENDMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to initial examination, please amend the above-identified application as follows:

IN THE SPECIFICATION

On page 1, immediately following the title, please insert the following sentence: --This is a nationalization of PCT/DK00/00697 filed December 14, 2000 and published in English.--

IN THE CLAIMS

Please amend claims 3, 5-8, 10-11, 18-20, 23-24, 28, 30, 32-39, 43-44, 50-51, 55-57, 60 and 62-63 as follows:

3. (amended) The prosthetic device according to claim 1, wherein the first polymeric component and the second polymeric component are compounded to form a bidispergent system.

5. (amended) The prosthetic device according to claim 1, wherein the second polymeric component is selected from polyacrylates, polystyrene, polyethers, polytetrafluorethylene, polyvinylalcohol, polyethylene, and polypropylene.

6. (amended) The prosthetic device according to claim 1, wherein the second polymeric component is cross-linked.

7. (amended) The prosthetic device according to claim 1, wherein the first and the second polymeric component comprises the same monomeric component.

8. (amended) The prosthetic device according to claim 1, comprising a third polymeric component, said third polymeric component being different from the first and/or the second polymeric component.

10. (amended) The prosthetic device according to claim 8, wherein the third polymeric component is grafted to the first and/or the second polymeric components.

11. (amended) The prosthetic device according to claim 1, wherein the chain length of the first polymeric component is above 100 monomer units.

18. (amended) A prosthetic device according to claim 1, wherein said device is adapted to alleviate conditions associated with worn cartilage by providing a spacer function and/or to exert pressure distribution in the joint when the joint is loaded and/or to provide at least part of the sliding/rotating movement of the joint by internal movement of at least part of the device.

19. (amended) A prosthetic device according to claim 1, wherein the device is capable of locking itself to an intra-articular component and thereby being fixed or retained in the joint cavity in a manner

which is substantially non-invasive with respect to cartilage and bone natively present in the joint cavity.

20. (amended) A prosthetic device according to claim 1, wherein the polymer material is obtained by cross-linking polyethylene, polypropylene or polyvinylpyrrolidone or combinations or copolymers thereof.

23. (amended) A prosthetic device according to claim 1, wherein the polymer material meets mechanical properties in that the E modulus (Young's modulus) is at least 10 MPa.

24. (amended) A prosthetic according to claim 1, wherein the device comprises more than one more unit.

28. (amended) A prosthetic device according to claim 1, wherein the polymer is subjected or further subjected to surface treatment to obtain optimised wetting ability and to obtain biocompatibility and resistance to heat treatment for sterilisation.

30. (amended) A prosthetic device according to claim 1, which is capable of locking itself to the intra-articular component by at least one element of the device surrounding the component in such a manner that displacement of the element is limited by interlocking with said component.

32. (amended) A prosthetic device according to claim 1, which device, when present *in situ*, comprises at least one ring-shaped element.

33. (amended) A prosthetic device according to claim 1 for the articulation of a hip of a human, which device is adapted so that it, when present *in situ* in the human hip joint cavity, comprises at least one element surrounding ligamentum capitis femoris.

34. (amended) A prosthetic device according to claim 1, in which the element which is adapted to surround the ligament when present *in situ*, has such a shape and such properties that it can be placed around the ligament and, when placed around the ligament, will stay interlocked with the ligament.

35. (amended) A prosthetic device according to claim 1 which is a hip endoprothese and wherein the element has a shape and properties permitting arranging the element around ligamentum capitis femoris.

36. (amended) A prosthetic device according to claim 30, wherein the element, when present *in situ*, permits the ligament to extend through the element and substantially exert its natural function on the joint.

37. (amended) A prosthetic device according to claim 1, having such shape and/or properties that it is capable of replacing or supplementing worn or damaged cartilage in the joint and/or is capable of preventing wear of the native cartilage of the joint.

38. (amended) A prosthetic device according to claim 30, wherein the element surrounding the intra-articular component constitutes the device.

39. (amended) A prosthetic device according to claim 1 wherein the

shape of the device mating the load bearing part of the joint is substantially circular.

43. (amended) A prosthetic device according to claim 1, wherein the thickness of the device is between 2-60 mm, such as between 6-40 mm, preferable 8-30 mm, more preferable about 10-20 mm, most preferable about 15 mm in the unloaded stage.

44. (amended) A prosthetic device according to claim 1, wherein the device comprises parts overlapping each other.

50. (amended) A prosthetic device according to claim 1, wherein the E modulus (Young's modulus) of the material of at least part of the device is at least 10 MPa, such as at least 13 MPa, preferably at least 16 MPa, more preferable at least 19 MPa, still more preferable at least 22 MPa, most preferable at least 25 MPa, such as at least 30 MPa or 50 MPa.

51. (amended) A prosthetic device according to claim 1, wherein the material constituting the device comprises polypropylene, preferably cross-linked polypropylene.

55. (amended) An instrument device for inserting a prosthetic device according to claim 1, comprising means for deforming the prosthetic device into a reduced volume or a slender shape and means for grasping the intraarticularintra-articular component to which the device is capable of interlocking.

56. (amended) The use of a prosthetic device for establishing slidability and/or distributing pressure in a joint of a vertebrate

such as a human, by inserting into the joint cavity of the joint a prosthetic device, preferably a prosthetic device as defined in claim 1, capable of locking itself to an intraarticularintra-articular component and thereby being fixed or retained in the joint cavity in a manner which is substantially non-invasive with respect to cartilage and bone natively present in the joint cavity.

57. (amended) A method for establishing slidability and/or pressure distribution in a joint of a vertebrate such as a human, comprising inserting into the joint cavity of the joint, a prosthetic device, preferably a prosthetic device as defined in claim 1, which is capable of locking itself to an intraarticularintra-articular component and thereby being fixed or retained in the joint cavity in a manner which is substantially non-invasive with respect to cartilage and bone natively present in the joint cavity.

60. (amended) A kit according to claim 58, wherein the instrument further comprises a handle.

62. (amended) A kit according to claim 58, wherein the resilient member of a.1) and the element surrounding the intraarticularintra-articular component of a.2) constitutes a solid prosthetic device.

63. (amended) A kit according to claim 58, wherein the intra-articular prosthetic device is a prosthetic device for insertion into a joint cavity of a joint of a vertebrate, such as a human, said device consisting of a biocompatible material comprising at least a first polymeric component and a second polymeric component, wherein the chain length of the first polymeric component is longer than the chain length of the second polymeric component.

REMARKS

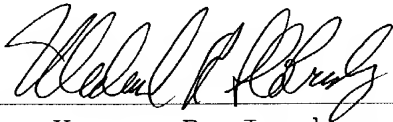

The foregoing Preliminary Amendment is requested in order to delete the multiple dependent claims and avoid paying the multiple dependent claims fee and to place the application in better form for examination.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE."

Early action on the merits is respectfully requested.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

3. (amended) The prosthetic device according to claim 1 [or 2], wherein the first polymeric component and the second polymeric component are compounded to form a bidispergent system.

5. (amended) The prosthetic device according to [any of the preceding claims] claim_1, wherein the second polymeric component is selected from polyacrylates, polystyrene, polyethers, polytetrafluorethylene, polyvinylalcohol, polyethylene, and polypropylene.

6. (amended) The prosthetic device according to [any of the preceding claims] claim_1, wherein the second polymeric component is cross-linked.

7. (amended) The prosthetic device according to [any of the preceding claims] claim_1, wherein the first and the second polymeric component comprises the same monomeric component.

8. (amended) The prosthetic device according to [any of the preceding claims] claim_1, comprising a third polymeric component, said third polymeric component being different from the first and/or the second polymeric component.

10. (amended) The prosthetic device according to [any of the preceding claims 8 or 9] claim_8, wherein the third polymeric component is grafted to the first and/or the second polymeric components.

11. (amended) The prosthetic device according to [any of the preceding claims] claim_1, wherein the chain length of the first polymeric component is above 100 monomer units.

18. (amended) A prosthetic device according to [any of the preceding claims] claim_1, wherein said device is adapted to alleviate conditions associated with worn cartilage by providing a spacer function and/or to exert pressure distribution in the joint when the joint is loaded and/or to provide at least part of the sliding/rotating movement of the joint by internal movement of at least part of the device.

19. (amended) A prosthetic device according to [any of the preceding claims] claim_1, wherein the device is capable of locking itself to an intra-articular component and thereby being fixed or retained in the joint cavity in a manner which is substantially non-invasive with respect to cartilage and bone natively present in the joint cavity.

20. (amended) A prosthetic device according to [any of claims 1 or 2] claim_1, wherein the polymer material is obtained by cross-linking polyethylene, polypropylene or polyvinylpyrrolidone or combinations or co-polymers thereof.

23. (amended) A prosthetic device according to [any of the preceding claims] claim_1, wherein the polymer material meets mechanical properties in that the E modulus (Young's modulus) is at least 10 MPa.

24. (amended) A prosthetic according to [any of the preceding

claims] claim 1, wherein the device comprises more than one more unit.

28. (amended) A prosthetic device according to [any of the preceding claims] claim 1, wherein the polymer is subjected or further subjected to surface treatment to obtain optimised wetting ability and to obtain biocompatibility and resistance to heat treatment for sterilisation.

30. (amended) A prosthetic device according to [any of the preceding claims] claim 1, which is capable of locking itself to the intra-articular component by at least one element of the device surrounding the component in such a manner that displacement of the element is limited by interlocking with said component.

32. (amended) A prosthetic device according to [any of the preceding claims] claim 1, which device, when present *in situ*, comprises at least one ring-shaped element.

33. (amended) A prosthetic device according to [any of the preceding claims] claim 1 for the articulation of a hip of a human, which device is adapted so that it, when present *in situ* in the human hip joint cavity, comprises at least one element surrounding ligamentum capitis femoris.

34. (amended) A prosthetic device according to [any of the preceding claims] claim 1, in which the element which is adapted to surround the ligament when present *in situ*, has such a shape and such properties that it can be placed around the ligament and, when placed around the ligament, will stay interlocked with the

ligament.

35. (amended) A prosthetic device according to [any of the preceding claims] claim 1 which is a hip endoprothese and wherein the element has a shape and properties permitting arranging the element around ligamentum capitis femoris.

36. (amended) A prosthetic device according to [any of claims 30-35] claim 30, wherein the element, when present *in situ*, permits the ligament to extend through the element and substantially exert its natural function on the joint.

37. (amended) A prosthetic device according to [any of the preceding claims] claim 1, having such shape and/or properties that it is capable of replacing or supplementing worn or damaged cartilage in the joint and/or is capable of preventing wear of the native cartilage of the joint.

38. (amended) A prosthetic device according to [any of claims 30-36] claim 30, wherein the element surrounding the intra-articular component constitutes the device.

39. (amended) A prosthetic device according to [any of the preceding claims] claim 1 wherein the shape of the device mating the load bearing part of the joint is substantially circular.

43. (amended) A prosthetic device according to [any of the preceding claims] claim 1, wherein the thickness of the device is between 2-60 mm, such as between 6-40 mm, preferable 8-30 mm, more preferable about 10-20 mm, most preferable about 15 mm in the

unloaded stage.

44. (amended) A prosthetic device according to [any of the preceding claims] claim_1, wherein the device comprises parts overlapping each other.

50. (amended) A prosthetic device according to [any of the preceding claims] claim_1, wherein the E modulus (Young's modulus) of the material of at least part of the device is at least 10 MPa, such as at least 13 MPa, preferably at least 16 MPa, more preferable at least 19 MPa, still more preferable at least 22 MPa, most preferable at least 25 MPa, such as at least 30 MPa or 50 MPa.

51. (amended) A prosthetic device according to [any of the preceding claims] claim_1, wherein the material constituting the device comprises polypropylene, preferably cross-linked polypropylene.

55. (amended) An instrument device for inserting a prosthetic device according to [any of claims 1-53] claim_1, comprising means for deforming the prosthetic device into a reduced volume or a slender shape and means for grasping the intraarticularintra-articular component to which the device is capable of interlocking.

56. (amended) The use of a prosthetic device for establishing slidability and/or distributing pressure in a joint of a vertebrate such as a human, by inserting into the joint cavity of the joint a prosthetic device, preferably a prosthetic device as defined in [any of the claims 1-53] claim_1, capable of locking itself to an intraarticularintra-articular component and thereby being fixed or

retained in the joint cavity in a manner which is substantially non-invasive with respect to cartilage and bone natively present in the joint cavity.

57. (amended) A method for establishing slidability and/or pressure distribution in a joint of a vertebrate such as a human, comprising inserting into the joint cavity of the joint, a prosthetic device, preferably a prosthetic device as defined in [any of the claims 1-53] claim 1, which is capable of locking itself to an intraarticularintra-articular component and thereby being fixed or retained in the joint cavity in a manner which is substantially non-invasive with respect to cartilage and bone natively present in the joint cavity.

60. (amended) A kit according to claim 58 [or 59], wherein the instrument further comprises a handle.

62. (amended) A kit according to [any of claims 58-61] claim 58, wherein the resilient member of a.1) and the element surrounding the intraarticularintra-articular component of a.2) constitutes a solid prosthetic device.

63. (amended) A kit according to claim 58 [any of the claims 58-62], wherein the intra-articular prosthetic device is a prosthetic device for insertion into a joint cavity of a joint of a vertebrate, such as a human, said device consisting of a biocompatible material comprising at least a first polymeric component and a second polymeric component, wherein the chain length of the first polymeric component is longer than the chain length of the second polymeric component [as defined in any of the claims 1-53].